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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,952	06/25/2003	Peter Lyon Harris	297912001602	3111

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MORRISON & FOERSTER, LLP
555 WEST FIFTH STREET
SUITE 3500
LOS ANGELES, CA 90013-1024

EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,952	HARRIS ET AL.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 14-26* is/are pending in the application.

4a) Of the above claim(s) *25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 14-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-21-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Newly submitted claims 25 and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a vascular prosthesis, classified in class 623, subclass 1.3.

II. Claims 25 and 26, drawn to a method of inducing non-laminar fluid flow, classified in class 604, subclass 9.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as one using a graft having a rectangular or circular (as opposed to generally oval) opening, and the process as claimed can be practiced with a materially different product such as one with a pump (rather than a decreased diameter portion) near the flared chamber portion.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and divergent required searches, restriction for examination purposes as indicated is proper.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25 and 26 are withdrawn from consideration as being directed to a non-elected invention (37 CFR 1.142(b) and MPEP § 821.03).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 4, "tubular portion" is a three-dimensional element, whereas "opening" is generally a two-dimensional feature, so the opening being "larger than the tubular portion" is deemed to be vague and indefinite; it is recommended that "diameter" or "cross-sectional area" be used to set forth the comparison limitation. In claim 21, lines 4 and 5, it is unclear whether volume, length, diameter, or some other measurement is implied by the term "smaller". Other errors were noted.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 7, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horiguchi, US 5,755,779. Since the decreased diameter portion is part of the tubular portion (instant claim 1, line 3), the Horiguchi opening diameters are certainly larger than tubular portion diameters at respective stricture portions **5**, **23a**, and **24a**. Regarding claim 3: column 3, lines 7-14 and 30-34. Regarding claims 14 and 16: column 1, lines 5-10; column 4, line 56. Regarding claim 19, oblique cross-sections are generally oval.

Claims 2, 4-6, 8-11, 15, 17, 20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horiguchi, US 5,755,779. Regarding claim 2 and others, the term "diameter" is defined as "[a] straight line segment passing through the center of a figure, esp. of a circle or a sphere, and terminating at the periphery" (*Webster's II New Riverside University Dictionary*, 1984), so the enlarged chambers at either end of the embodiment depicted in Figure 4 comprise a first diameter parallel to an axis of the tube and a second diameter transverse to said axis. The enlarged chambers having a length along the longitudinal dimension of the tube so as to be greater than said second or transverse diameter would have been obvious in order to provide adequate material for anastomosing to the patient's natural blood vessels. A final concave portion is defined by the interior surface at each opening. Regarding claim 4 and others, generally outwardly concave and convex transitional regions would have been inherent from

Figures 2 and 3 and column 5, lines 1-4. Regarding claim 6, diameters of about 14 mm would have been obvious in order to accommodate blood vessels of complementary size. Regarding claim 15 and others, ePTFE was well known in the art at the time of the present invention and would have been an obvious "artificial" material in view of its hemocompatibility and other favorable properties.

Claim 23 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Gore advertisement, published prior to June 21, 1989 (one page). The ePTFE structure pictured on the right comprises an enlargement at a distal end because of the ring, which defines an outer diameter larger than an outer diameter of the tubular part.

Claims 1-5, 7-11, and 14-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lunn, US 5,476,506. As seen from the drawings, "the end portions **16** and **18** of the graft **10** have greater diameters in the relaxed state than the central portion **20**" (column 4, lines 16-18), with "relaxed" being further explained at column 6, lines 28-32, for example. The decreased diameter portion corresponds to the trough **28** nearest a respective end formation **16** or **18**. The graft is *capable* of being connected to an opening, such as an ostium, whether or not such was the intent. Regarding claim 2, the first diameter or longitudinal dimension of the enlarged chamber **16** or **18** is inherently longer than a transverse diameter thereof, at least in said relaxed state (Figure 5A; column 5, lines 24-35); outwardly convex and concave transitional regions are shown in Figure 3; further concave and convex portions are depicted in Figure 2. Regarding claim 3, blood flow with at least a partially non-laminar nature would have been inherent from the different luminal diameters involved. Regarding claim 15 and others: column 5, line 66.

Claims 6 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lunn, US 5,476,506. Regarding claim 6, the particular dimensions would have obvious to the ordinary practitioner in order to accommodate a range of blood vessel sizes. Regarding claim 23, ePTFE would have been obvious from the contemplated alternatives to weaving and knitting (column 6, lines 1-5) and from the prevalence of ePTFE in the art.

The Applicant's remarks have been reviewed but are deemed to be moot in view of the new grounds of rejection, which were necessitated by the language added to claims 1, 18, and 21, and by the new claims. Therefore:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738